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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DELLA, JAYMI E	

ART UNIT	PAPER NUMBER
4137	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,631	HILLELY, RON	
	Examiner	Art Unit	
	JAYMI DELLA	4137	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 19, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *33* is/are allowed.

6)☒ Claim(s) *1-32 and 34-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :09/28/2006, 07/21/2008, 03/15/2009.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: on page 1, line 7, and page 12, line 8, the word "an" should be replaced with "a".

2. The use of the trademark DELRIN® and TEFLON® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show "cryoprobes 290" on page 25, line 30 as described in the specification. The drawings also fail to show "circular markings" of claims 31 and 68. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d).

4. The drawings are objected to because of poor line quality and solid black shading is not permitted as shown in Figures 7, 9-11.

5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 31 and 68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. For both claims, it is unclear as to what "standardized conditions" are. For purposes of examination, it will be examined as meaning the standardized conditions for any type of ablation, such as cryoablation, required for effectively destroying a tissue. For cryoablation, standard conditions are

approximately -40C or cooler as explained by Schatzberger (U.S. Patent No. 6,142,991). For cyroablation purposes, the temperature at the surface of the ice-ball is 0C, and declines exponentially towards the center of the ball such that an isothermal surface of about -40C is typically located within the ice-ball substantially at the half way between the center of the ball and its surface. (Column 1, Lines 24-30)

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 37-70 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

10. Claims 37-70 are directed to a device with a probe inserted into the body of a patient. Because the claim positively recites a part of the human body, it is directed to nonstatutory subject matter.

11. Applicant is advised to change the language of claim 37 to read: A device for guiding a therapeutic probe to a treatment target, comprising a template operable to be rigidly affixed to an orientation probe capable of being insertable into the body of a patient, which template comprises at least one probe guide operable to constrain movement of a therapeutic probe inserted therethrough to movement in a controlled direction, such that if an orientation probe that is capable of being insertable into the body of a patient in such manner that a distal portion of said orientation probe is positioned within said treatment target, and said template is rigidly affixed to said

orientation probe, then a therapeutic probe capable of being inserted into the body of a patient through said at least one probe guide will be constrained to move towards said treatment target.

12. Applicant is advised to change the language of claim 67 to read: The device of claim 37 wherein said template further comprises circular markings indicating boundaries of expected tissue destruction when ablation probes are inserted through probe guides of said template and then capable of being inserted into a body of a patient and said probes are activated to ablate body tissues under standardized conditions.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-6, 11-12, 16-24, 25-29, 34, 37-40, 42-44, 49-50, 53-64, 66, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by Downey et al. (U.S. Patent No. 6,206,832). Note to Applicant: claim 1 does not require positively any sequence of steps. Therefore, this claim reads on a process where steps (a) and (b) are performed simultaneously.

15. Concerning claims 1, 3, 5, 11-12, 16-23, 25-29, 37-40, 42-44, 49-50, 53-64, and 69 Downey et al. discloses a method for facilitating the placement of a medical instrument into a target tissue (Column 5, Lines 23-25). Apparatus (10) comprises a reference plate (15) that has a plurality of regularly spaced apertures (30), in the form of Cartesian grid, that pass through reference plate (15), and are relative to an ultrasonographic transducer . Apertures (30) are sized to allow at least one medical instruments, such as a biopsy needle (40) pass through. (Column 5, Lines 34-40) Apparatus (10) may be adapted to other medical instruments, such as therapeutic cryosurgical probes, guidance sheathes, thermocouples and the like (Column 7, Lines 55-64). Thus, any type of probe that is used for percutaneous treatment of body tissues can be used. Apertures (30) are provided with an internal adjustment means (50), which comprises a ball (55) disposed within complementary socket (60). Each ball (55) has a passageway (65) sized to receive a portion of biopsy needle (40) that forms part of aperture (30) and is rotatable around axle (70). (Column 6, Lines 8-20). It is inherent in Downey et al.'s method that the medical instrument introduced into passageway (65) is a rigid fit as Downey et al. discloses that only rotation of ball (55) around axle (70) permits movement of the needle. Thus, the diameter of passageway (65) is only slightly larger than the diameter of the medical instrument placed through, and once inserted, forms a pressure fit to secure the instrument in place. Once transducer (45) is placed in the patient, apparatus (10) is initialized so that the orientation of face plane (35) and a specific reference aperture on Cartesian grid is referenced to transducer (45). A three-dimensional image of the target tissue is displayed on the computer and a digital image

representation of the Cartesian coordinate grid is superimposed over the three-dimensional image such that the Cartesian grid of apertures (30) corresponds spatially with the imaged region to create a positioning image. The desired target location for the medical instrument is inputted into the computer and the optimal trajectory of insertion in three dimensions via an appropriate apertures (30) in reference plate (15) is determined. (Column 6, Lines 39-58) Downey et al.'s method simultaneously inserts a medical instrument into the body of a patient while rigidly affixing that same medical instrument to a template. If more than one medical instrument is required for insertion, the steps can be repeated (Column 7, Lines 4-5). When at least one medical instrument is inserted into the patient, the trajectory of the needle can be monitored using real-time three-dimensional ultrasonographic imaging (Column 7, Lines 8-11). Internal adjustment means (50) provides the practitioner with the ability to make minor adjustments to the trajectory of the instrument during placement and within the target tissue (Column 7, Lines 16-23). Because each aperture has an individual internal adjustment means, each aperture can be made to have a commonly oriented axes direction. Each aperture axis will be parallel to the longitudinal probe axis fixed within ball (55); therefore, when ball (55) rotates around axle (70), both the aperture axis and probe axis rotate in parallel. The internal adjustment means provides approximately thirty to fifty degrees range of movement for the medical instrument placed through the aperture from an axis perpendicular to the reference means' face plane (Column 6, Lines 31-38). Since plate (110) includes a net of apertures (120) as illustrated in Fig. 8,

as probes are inserted into the apertures, the 1st inserted probe must inherently provide spatial relationship to a treatment target.

16. Concerning claims 2, 6, and 24 Downey et al. teach that if more than one medical instrument is required for insertion into the target tissue after a first cryosurgical probe, that inherently provides spatial relationship to the treatment target, is inserted, the steps of determining the desired target location for the medical instrument can be repeated: inputting this information into the computer, calculating the optimal trajectory of insertion, adjusting the reference plate such that the orientation of the face plane is perpendicular to the calculated trajectory path, inserting the medical instrument, and using the internal adjustment means to adjust the location of the probe (Column 6, Lines 53-67 and Column 7, Lines 7). Thus, since the steps for inserting a 1st medical instrument (in this case, a 1st cryosurgical probe) is repeated (if desired) for a 2nd medical instrument, which is also a cryosurgical probe, then a second cryosurgical probe is inserted, which inherently would ablate tissue.

17. Concerning claim 4, Downey et al. disclose that the three-dimensional imaging used can be ultrasound, Computer Tomography (CT), or Magnetic Resonance Imaging (MRI) (Column 7, Lines 38-40).

18. Concerning claims 28-29, and 65-66 Downey et al. disclose internal adjustment means (50), comprising a ball (55) disposed within complementary socket (60). Each ball (55) has a passageway (65) sized to receive a portion of the medical instrument (40) that forms part of aperture (30) and is rotatable around axle (70). (Column 6, Lines 8-20; Fig. 6). The internal adjustment means allows the practitioner to adjust

concentrate or disperse the distal portions of a plurality of probes inserted through the guide as illustrated in Fig. 6.

19. Concerning claim 34, Downey et al. discloses that prostate carcinoma is a common type of cancer that can be treated using the minimally invasive percutaneous cryosurgical technique disclosed (Column 1, Lines 37-40).

20. Claims 37, 47-49, 53-58, 63, 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by West et al. (U.S. Patent No. Des. 260,727).

21. Concerning claims 37, 47-49, 53-58, 63, and 69-70, West discloses a device for holding nails that is capable of being used to guide a probe to a treatment target within the body of a patient. It has a template that can be rigidly affixed to a probe. The template comprises multiple guides to control movement of probes inserted therethrough. Once a probe is inserted into the body such that the probe's distal portion is positioned within the treatment target, West et al.'s device can be rigidly affixed to this probe by squeezing the handles, positioning the first probe within a probe guide, and releasing the handles, such that the probe is rigidly affixed to the template via pressure clamping. Multiple therapeutic probes can then be inserted through the template guides into the body. (Fig. 1)

22. Claims 37, 42, 47-49, 53-58, 63, and 69-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Zurinski et al. (U.S. Patent No. 4,542,747).

23. Concerning claims 37, 42, 47- 49, 53-58, 63, and 69-70, Zurinski et al. disclose an ultrasonic applicator with end pieces (64) and (66) that are used as operating controls or hand grips. Partial bodies (4) and (6) are connected to one another in such

a way that, when in the closed position, two guide grooves (8) and (10) form guide channel (38) that serves to guide biopsy needle (37) (Column 6, Lines 11-15). Guide grooves (8) and (10) are designed with a semicircular cross-section, so that when partial bodies (4) and (6) are put together, a round cross-section for guide channel (38) is formed in the closed position. The two guide grooves have only a little deeper than the half-diameter of needle (37), making them fit snugly in guide channel (38). (Column 7, Lines 16-24) Guide channels (50, 52, 54) are located at desired points along the applicator (Column 8, Lines 14-17). When force is exerted that overcomes spring (72), partial bodies (4) and (6) swivel open. Between end pieces (64) and (66), pressure spring (72) is placed, insuring that partial bodies (4) and (6) are normally held in a closed position, thus creating a pressure clamp. (Column 8, Lines 26-43; Fig. 10) Biopsy device (37) is inserted through guide channel (38) into the object to be investigated with ultrasonic imaging (Column 6, Lines 39-42). A biopsy device is a type of probe, as probe is defined as a slender medical instrument used for exploration (Merriam Webster Dictionary).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

25. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
26. 4. Considering objective evidence present in the application indicating obviousness or nonobviousness. Considering objective evidence present in the application indicating obviousness or nonobviousness, claims 7-8 and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downey et al. et al. (U.S. Patent No. 6,206,832) as applied to claims 1 and 37 above, in view of Zvuloni et al. (U.S. Patent No. 6,706,037).

27. Concerning claims 7-8 and 45-46, Downey et al. fail to disclose cryoprobes operable by Joule-Thomson cooling or heating. However, Zvuloni discloses a cryosurgical apparatus using Joule-Thomson heat exchanges with passageway (10) that includes a plurality of orifices for passage of high-pressure gas so as to cool or heat selective portions of the device. (Column 12, Lines 42-48). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to use Joule-Thomson cooling and heating cryoprobes as Zvuloni discloses that two-stage cooling with Joule-Thomson heat exchangers presents the advantages of more rapid and more efficient cooling than is possible in a single Joule-Thomson cooling stage (Column 3, Lines 1-6). This method and apparatus for improving Downey et al.'s method and apparatus for guiding medical instruments was within the ordinary ability of one of ordinary skill in the art based on the teachings of Zvuloni.

28. Claims 13-15, 31 51-52 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downey et al. (U.S. Patent No. 6,206,832) as applied to claims 1 and 37 above, in view of Schatzberger (U.S. Patent No. 6,142,991).

29. Concerning claims 13-14 and 51-52, Downey et al. fail to disclose an orientation or therapeutic probe with a set of marks useable to measure a distance of insertion. Schatzberger discloses a cryosurgical method and apparatus that uses cryosurgical probes with a scale for indicating depth of penetration into the target tissue (Column 11, Lines 53-54). At the time of the invention, it would have been obvious to one of ordinary skill in the art to substitute Downey et al.'s cryoprobes with Schatzberger's functionally equivalent marked cryoprobes in order to provide a means for measuring a distance of insertion.

30. Concerning claim 15, Downey et al. fail to disclose inserting a therapeutic probe to a distance having a selected relationship to a measured distance of insertion to an orientation probe. Schatzberger discloses inserting a plurality of cryosurgical probes to a specific depth sequentially through apertures (120) of guiding element (115) into the treatment target. At the time of the invention, it would have been obvious to one of ordinary skill in the art that it would naturally flow from Schatzberger's method that each inserted probe would have a predetermined relationship to all other probes from the cryosurgical procedure planning stage in order to effectively destroy the target tissue without damaging non-target tissue.

31. Concerning claims 31 and 68, Downey et al. fail to teach that the template comprises circular markings indicating boundaries of tissue destruction expected when

ablation probes are inserted through the probe guides and the ablation probes are activated to ablate the body tissue under standardized conditions. The term "standardized condition" is defined as explained in paragraph 7 above. At the time of the invention, it would have been obvious to one of ordinary skill in the art to use standardized conditions normally used during cryoablation procedures to provide an environment to ensure repeatable results and also ensure the probe are operating at a condition recognized by the art to be suitable for such application thereby preventing unnecessary damage to surrounding good tissues.

32. Schatzberger discloses a method and apparatus that applies an imaging device such as ultrasound, MRI or CT to form a three-dimensional grid of the treatment target (Column 10, Lines 59-63). A guiding element (115) is connected to housing element (128) via a connecting arm (126). Guiding element (115) is in the form of a plate (110) having a net of apertures, each aperture serving for insertion of a cryosurgical probe. (Column 11, Lines 1-5) A net of marks (112) is provided on image (114) being accurately correlated to the net of apertures (120) on guiding element (115). Marks (112) on image (114) sign the exact locations of the ice-ball centers formed at the end of cryosurgical probes inserted through apertures (120). Sets of image (114) taken at various depths provides a three-dimensional grid of the treatment target and is used for planning the cryosurgical procedure. (Column 11, Lines 10-30; Fig. 9) A plurality of cryoprobes is inserted through apertures (120) of guiding element (115) into the treatment target. Each probe is inserted to a specific depth, providing local effective treatment to distinct segments of the treatment target while avoiding damaging other

tissue segments. (Column 11, Lines 46-52) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use the marks (112) suggested by Schatzberger in order to indicate boundaries of tissue destruction expected where the probes are inserted as they are functionally equivalent to circular markings.

33. Claims 30 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Downey et al. (U.S. Patent No. 6,206,832) as applied to claims 1 and 37 above, in view of Whitmore, III et al. (U.S. Patent No. 5,931,786).

34. Concerning claims 30 and 67, Downey et al. fail to disclose a template made of ertacetal resin. Whitmore, III et al. discloses that all the components of a template grid support apparatus for medical instruments can be fabricated or cast of a plastic, with engineering thermoplastics, such as DELRIN® (Column 4, Lines 10-16). Because both Downey et al. and Whitmore, III et al. teach the use of a template to guide medical instruments to a selected treatment target, it would have been obvious to one of ordinary skill in the art at the time of the invention to use a template grid support apparatus made of ertacetal resin for Downey et al.'s template as such an art is recognized suitable template material for medical instruments.

35. Claims 35-36, are rejected under 35 U.S.C. 103(a) as being unpatentable over Downey et al. (U.S. Patent No. 6,206,832) as applied to claim 1 in view of Morra et al. (*Choices*).

36. Concerning claims 35-36, Downey et al. fail to disclose that a portion of the treatment target is within the liver or the kidney. At the time of the invention, it would have been obvious to one of ordinary skill in the art to adapt Downey et al.'s minimally

invasive percutaneous cryosurgical technique for use on with different treatment targets, such as the liver or kidney, because it is a common practice in the art to use cryosurgery for treatment of cancer of the prostate, liver, and kidney as exemplified in the teachings of Morra et al (Page 181) in order to gain the benefits of ablating unwanted tissue at the target site.

37. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Downey et al. (U.S. Patent No. 6,206,832) as applied to claim 38 in view of Kelly et al (U.S. Patent No. 5,483,961) and Migdal (*MRI Guided Hepatic Cryotherapy Using the CRYO-HIT™ System*). .

38. Concerning claim 41, Downey et al. fail to disclose an orientation probe used as a positioning reference for a second inserted medical instrument. However, Kelly et al. disclose using a stylus (25) and displaying the position of the tip of the stylus using CT or MRI images to orient a surgeon with direct real-time comparison of the position of the stylus (25) tip in the surgical field with respect to the patient's anatomy (Column 8, Lines 66-67 and Column 9, Lines 1-4). As illustrated in Fig. 2 and Fig. 8, stylus (25) is a **solid probe devoid of differentiated internal parts** in the distal end that is inserted into the patient. Furthermore, it is known in the art to place an MR compatible 18G needle into the treatment target, where this needle is used as a reference positioning means, and then place a treatment needle such as a cryoprobe based on the confirmed position of the reference needle as exemplified in the teachings of Migdal (page 2) At the time of the invention, it would have been obvious to one of ordinary skill in the art to use a solid positioning needle which is devoid of differentiated internal parts as the first medical

instrument inserted into Downey et al.'s guide because as noted above: a) a solid probe devoid of differentiated internal parts is an art recognized effective reference positioning means; b) it is also known to sequentially insert a reference positioning probe and a treatment probe to a target tissue. A preference on whether to use a treatment probe as suggested by Downey et al or simply a solid probe devoid of differentiated internal parts as a 1st medical instrument to be inserted in the process of Downey et al is taken to be well within the purview of choice in the art. There is none, but only the expected result of using the 1st medical instrument as a reference positioning probe would have been achieved in the modified process of Downey et al instead of using it as both a reference positioning probe and treatment probe.

39. Claims 1, 9-12, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zurinski et al. (U.S. Patent No. 4,542,747) in view of Downey et al. (U.S. Patent No. 6,206,832).

40. Concerning claims 1, 9-12, 26, and 32, Zurinski discloses an ultrasonic applicator for biopsy with two partial bodies (4,6) arranged parallel to one another with guide channels (50,52,54) intended to snugly receive a biopsy needle, operable by exerting a force that overcomes spring (72) that causes partial bodies (4,6) to separate as discussed in Paragraph 23 above (Column 7, Lines 16-24 and Column 8, Lines 14-17 and 26-43). Zurinski et al. fails to disclose a method for guiding a therapeutic probe to a treatment target comprising: inserting an orientation probe into the body of a patient and positioning the probe so that it has a known spatial relationship to a treatment target; inserting at least one therapeutic probe through one probe guide into the body of

the patient. Downey et al. teaches alternatively inserting a single medical instrument (in this case, a biopsy needle) or multiple medical instruments (plural biopsy needles) into the body of a patient through a template's guide holes as discussed in Paragraph 14 above. At the time of the invention, since both Zurinski and Downey et al. are both drawn to a process of inserting biopsy needles, it would have been obvious to one of ordinary skill in the art to modify Zurinski and insert more than one biopsy needles, because it is a common practice in the art to either insert a single biopsy needle or multiple biopsy needles into a patient's target area as exemplified in the teachings of Downey. The incentive for one in the art to insert two biopsy needles instead of only one biopsy needle in the process taught by Zurinski et al would have simply been to obtain the self-evident advantage of taking biopsy samples in two different areas of the treatment target thereby saving time and discomfort to the patient by obviating the need to take two samples at different times or two different procedures. . It directly follows that the first probe can naturally function as an orientation probe because the distance between the probe guides is fixed and known in the device of Zurinski.

Allowable Subject Matter

41. Claim 33 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

42. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

43. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

44. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D./
Examiner, Art Unit 4137
5/5/2009

/Sam Chuan C. Yao/
Supervisory Patent Examiner, Art Unit 4111